SECTION 13 D – REUSE OF SINGLE USE DEVICES

I. APPLICABILITY. This policy applies to all departments, activities, and services throughout DHCN.

II. GENERAL INFORMATION. Equipment and supplies designated for single patient use are to be used once and discarded. Strict federal regulations govern the use of a third party reprocessor for the reprocessing of single use devices (SUDS). Requests for an exception to policy should be submitted to the Chief, Perioperative Nursing and the Hospital Infection Control Officer in writing. All requests will be forwarded to the Surgery PI Committee and the Materiel Standardization Committee for consideration.

A. If there are concerns about the manufacturer's label or absence of direction about whether a device is multiple or single use, contact Infection Control or Surgical services.

III. BACKGROUND. The U.S. Food and Drug Administration (FDA) has finalized a very strict policy on the reuse of medical devices labeled for single-use. Their primary goal is to protect the health of the public by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe, effective, and evidence- based. The public expects and the law requires all medical devices to be safe, effective and manufactured IAW good manufacturing practices (GMPs). Therefore, the FDA has concluded that the practice of reprocessing SUDs merits increased regulatory oversight.

A. Medical single-use devices (SUDs) are intended by the original manufacturer to be used on one patient during one medical procedure and discarded. A SUD is not intended for reused on another patient or on the same patient at another time.

B. Multiple use devices are intended to be used more than one time and include instructions for decontamination and resterilization. Original manufacturers are required to prove a device is safe for single use or multiple uses. Strict federal regulations govern the use of a third party reprocessor for the reprocessing of SUDS. The Food and Drug Administration (FDA) issued regulatory guidance on August 14, 2000, for third-party and hospital reprocessors regarding their responsibility as manufacturers engaged in reprocessing devices labeled for single use. Under the FDA guidance, third-party and hospital reprocessors are subject to the same FDA guidelines and scrutiny as original medical device manufacturers.

C. Examples of SUDS include: Surgical saw blades; Laparoscopy scissors; Endotracheal tubes; Electrosurgical electrodes and pencils; and Biopsy forceps.

D. The FDA has categorized SUDs into three risk categories.

1. Class I devices are devices with low patient risk, such as orthopedic surgical drills.

2. Class II devices are considered to have moderate patient risk, such as a cardiac catheter. Unless exempt by the FDA, these devices require a premarket

notification submission to the FDA that provides detailed information about the process and the device. The FDA will then determine the safety and effectiveness of the device.

3. Class III devices have a high patient risk and are the most regulated. Examples include: a cardiac ablation catheter and balloon angioplasty (PTCA) catheters. Class III devices require a third-party or hospital reprocessor to submit a premarket approval application that includes valid scientific evidence demonstrating the safety and effectiveness of the reprocessed device. The FDA also requires a thorough inspection of a reprocessing facility before granting approval.

E. FDA guidance equitably applies existing regulations to original equipment manufacturers (OEMs), third parties, and hospitals to minimize risks associated with reprocessed SUDs. This guidance applies to third-party & hospital SUD reprocessors, but it does not apply to:

- permanently implantable pacemakers
- "open-but-unused" SUDs
- healthcare facilities that are not hospitals
- and hemodialyzers.

F. Requests for an exception to policy should be submitted to the Chief, Perioperative Nursing and the Hospital Infection Control Officer in writing. All requests will be forwarded to the Surgery PI Committee and the Materiel Standardization Committee for consideration.

Additional Information and Resources:

Division of Small Manufacturers Assistance (DSMA):

  - Phone (301) 443-6597; (800) 638-2041
  - Facts-On-Demand (800) 899-0381 or (301) 827-0111
  - Device Advice website http://www.fda.gov/cdrh/devadvice/11.html
- CDRH website has:
  - Quality System Inspection Technique (QSIT) Handbook
  - Design Control Guidance
  - Medical Device Quality Systems Manual
    http://www.fda.gov/cdrh/dsma/cgmphome.html
    http://www.fda.gov/cdrh/index.html

Reuse Website: http://www.fda.gov/cdrh/reuse/index.shtml

Examples of Reprocessed Single-Use Devices; Appendix A
http://www.fda.gov/cdrh/reuse/1168a.html

Medical Device Reporting (MDR) http://www.fda.gov/cdrh/mdr.html

Standards http://www.fda.gov/cdrh/stdsprog.html
Quality System/Good Manufacturing Practice
http://www.fda.gov/cdrh/dsma/cgmphome.html

Documents

Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals;Final Guidance for Industry and FDA Staff (8/14/00)
http://www.fda.gov/cdrh/comp/guidance/1168.pdf

Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff (6/1/01)
http://www.fda.gov/cdrh/ode/guidance/1331.pdf

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA (7/30/01)
http://www.fda.gov/cdrh/comp/guidance/1392.pdf

Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by theOriginal Equipment Manufacturer for Single Use; Final Guidance for Hospital Reprocessors and FDA Staff (4/24/01)
http://www.fda.gov/cdrh/osb/guidance/1334.pdf

Frequently Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third Parties and Hospital Reprocessors; Final Guidance for Industry and FDA Staff (7/6/01) http://www.fda.gov/cdrh/ohip/guidance/1333.pdf

Letter to Hospitals Re: Reprocessing of Single Use Devices (4/23/01)
http://www.fda.gov/cdrh/reuse/042301_reuse.html

Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (4/96) http://www.fda.gov/cdrh/ode/198.pdf

Questions & Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities (9/3/96)
http://www.fda.gov/cdrh/ode/1198.html

Updated 510(k) Sterility Review Guidance (K90-1), Final Guidance for Industry and FDA (11/16/01) http://www.fda.gov/cdrh/k90-1.html

Compliance Policy Guide (CPG 7124.16) Section 300.500. Reuse of Medical Disposable Devices (9/24/87) http://www.fda.gov/cdrh/comp/cpgreuse.pdf